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NRC

030-21081

Corporate Headquarters

649 California Avenue
Wahiawa, Hawaii 96786
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1985 AUG 19 PM 1:51

REGION VIAE

13 August 1985

U.S. N.R.C.
12 FEE MGMT BRANCH

85 SEP 26 AM 10:54

RECEIVED

Ms. Beth Riedlinger
Nuclear Regulatory Commission, Region V
1450 Maria Lane
Walnut Creek, CA 94596

Dear Ms. Riedlinger:

Enclosed is a license amendment application for NRC License Number 53-23440-01. The changes requested are as follows:

1. The activity per source is increased from 500 mCi to 800 mCi to be consistent with our custom device approval.
2. The radiation survey program has been changed. Isodose curves around the OsteoAnalyzer and normalized to 800 mCi are provided and the requirement to survey the OsteoAnalyzer each time a new source is installed has been deleted. The requirement to survey the storage cabinet each time another source is put in is also deleted, since the sources are shipped to us with a RADIOACTIVE - WHITE I label.
3. Paragraph 3.2.4. of the Hands-On Training has been deleted in accordance with your letter of 22 July 1985.

Your prompt response to this application would be appreciated.

U.S. N.R.C.
12 FEE MGMT BRANCH

Sincerely,

OSTEON, INC.

Philip J. Manly

Philip J. Manly
President

Note: License fee was sent
directly to General Jackson.

Aug-2-V

encl.

Applicant
Check No.	007714
Amount	\$110.30
Type of Fee	Amendment
Date Check Recd.	8/20/85
Received By	Jacques

8510310472 850826
REGS LIC30
53-23440-01 PDR

70246

LICENSED MATERIAL

Item 5 - Radioactive Material

Element and mass number: I-125

Chemical and/or physical form: sealed source (AECL C-235 source in AECL C-236 source holder)

Maximum amount which will be possessed: 5 sources at 800 mCi per source

Item 6 - Purposes For Which Licensed Material Will Be Used

Use in Model SPSHAXXX bone mineral analyzer for performance testing and development, training, and demonstration. The Model SPSHAXXX bone mineral analyzer has received custom device approval from the NRC.

RADIATION SAFETY PROGRAM

Item 10 - Radiation Safety Program

1. SURVEY PROGRAM

1.1. The use of the sealed source in the bone mineral analyzer consists of placing the source in a fixed geometry position in the analyzer. Once it is in place, the shielding and beam direction cannot change unless the analyzer suffers some damage.

1.2. A detailed radiation survey has been performed with the source in an OsteoAnalyzer. The results of the survey are shown in Figure 1 to 3, normalized to a full strength 800 mCi source. A decay curve is also provided in Figure 4 so that the radiation levels for any source strength can be estimated from Figures 1 to 3.

2. RECORDS MANAGEMENT PROGRAM

2.1. Records of source receipt and transfer shall be kept for at least 5 years.

2.3. Records of leak tests of sealed sources shall be kept for at least 5 years.

2.4. Personnel exposure records shall be kept indefinitely.

2.5. Records of source disposals shall be kept indefinitely.

2.6. Records shall be reviewed for completeness and accuracy on a semi-annual basis by the Radiation Safety Officer or his designate.

3. LEAK TEST PROCEDURES

3.1. Leak tests shall be performed on sources in use every six months. The leak tests shall be able to detect 0.005 uCi of activity. Results of the leak tests shall be documented. Leak tests shall be performed according to the following procedures:

3.1.1. Take a canvas wipe and wipe it around the joint between the source holder and source cap. Place the wipe in the folded paper envelope used to hold it.

3.1.2. Calibrate the laboratory counter with a mock iodine source. Count the mock iodine source for one minute.

3.1.3. Count background for one minute. Calculate the conversion factor for the detector as follows:

$$K = uCi / (C_s - C_b)$$

uCi = source activity

C_s = source cnts per min

C_b^s = bkgd cnts per min

3.1.4. Remove the source and take a one minute background count. Calculate the minimum detectable activity (MDA) and minimum detectable count rate (MDCR) according to the following formulas:

$$MDCR = 1.64 \times \sqrt{2 \times C_b}$$

$$MDA = K \times 1.64 \times \sqrt{2 \times C_b}$$

3.1.5. Count the wipe for 1 minute. If the measured count rate is less than MDCR, record the activity as <MDA. If the measured count rate is greater than MDCR, calculate and record the actual activity.

3.1.6. With typical counting equipment, this counting procedure will result in a MDA of less than 0.0005 uCi.

4. INSTRUCTION TO PERSONNEL

4.1. Personnel who use the I-125 sealed sources in the OsteoAnalyzer will either be specifically authorized by the license, or will have completed the in-house training program for users of the OsteoAnalyzer.

5. PACKAGE RECEIVING AND OPENING PROCEDURES

5.1. The I-125 sources are also less than Type A quantities of radioactive material. Consequently, no radiation surveys are required on receipt of the package. When shipped from the manufacturer, the packages carry a WHITE-I radioactive label, indicating that radiation levels on the surface are less than 0.5 mR/hr.

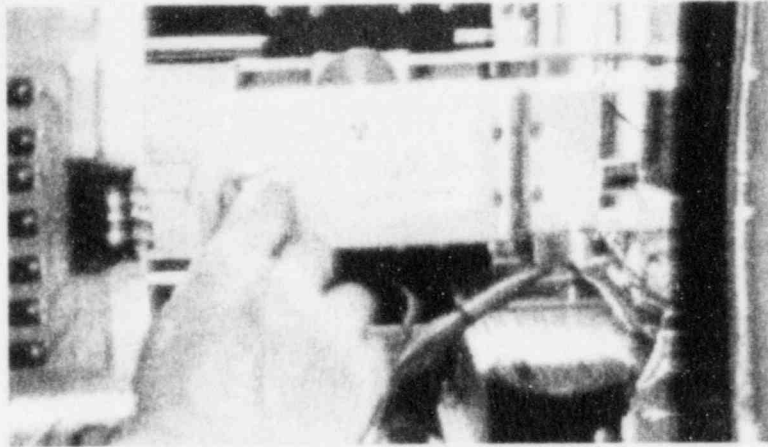
5.2. Open the outer shipping container. Open the inner shipping container with the brass source capsule. Take a canvas wipe and wipe the brass source capsule. Analyze the wipe to verify₂ there is no removable contamination greater than 200 dpm/100 cm².

5.3. Verify the serial number on the source against the serial number on the shipping documents. Log the receipt of the source into the source receipt log.

5.4. Leave the source in the original shipping container until it is actually installed in the analyzer.

6. SOURCE REPLACEMENT PROCEDURES

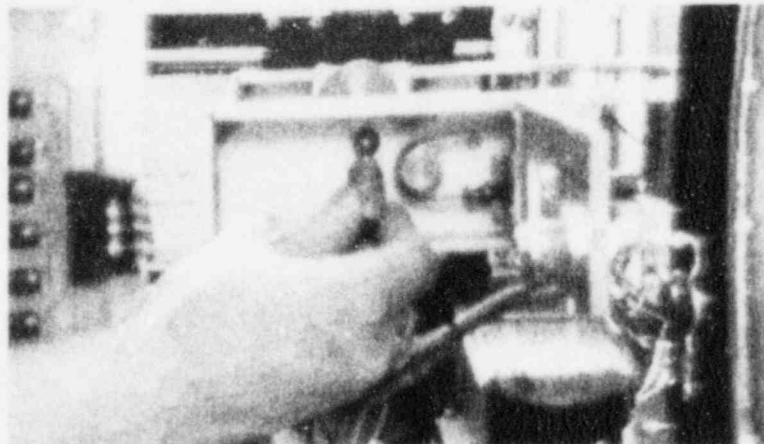
6.1. Remove the outer cover of the scanner unit. Using the key for the source compartment, unlock and remove the cover from the source compartment.



6.2. Unscrew the source from the receptacle in the source compartment. Immediately screw on the brass cap on the source. Make sure the end of the source capsule with the threads is always pointed away from you when the cap is not on.

6.3. Place the source in the shipping container to be returned to the manufacturer.

6.4. Remove the new brass source capsule with the brass cap attached from the shipping container. Unscrew the cap from the source and screw the source into the receptacle in the source compartment. Make sure the end of the source capsule with the threads is always pointed away from you when the cap is not on.



6.5. Using the key, lock the source compartment cover in place. Remove the key and store it in a secure location.

6.6. Replace the cover on the scanner unit.

7. SOURCE PACKAGING AND SHIPPING PROCEDURES

7.1. Place the source with the cap tightly screwed on in the foam insert from the original shipping container.

7.2. Place the foam insert in the original inner container (metal can) and tape the lid on the can with fabric-backed tape.

7.3. Place the metal can in the original outer shipping box and tape the box closed with security tape.

7.4. Remove old shipping labels, packing slips, and other old labels from the box. Make sure the words "RADIOACTIVE MATERIAL", "TYPE 'A' PACKAGE", "I.A.E.A. C.T.C-12B25", and the manufacturer's name and address are still clearly legible on the box.

7.5. Place two new RADIOACTIVE WHITE-I labels over the old ones on the box. Enter I-125 as the contents. Calculate and enter the activity of the source.

7.6. Place a shipping label on the box with the name and address of the facility shipped from and shipped to.

7.7. Write or stamp the words "RADIOACTIVE MATERIAL, N.O.S." and "UN2982" on the box in letters at least 1/2" high.

7.8. Fill out the shipping papers for the shipment. The proper shipping name for the source is "Radioactive Material, N.O.S. (Iodine-125)" and the proper classification is "UN2982".

8. INVENTORY REQUIREMENTS

8.1. An inventory of all sources in use and in storage shall be made every six months. Records of the semi-annual inventories shall be kept.

9. EMERGENCY PROCEDURES

9.1. The low energy gamma and x-rays emitted from the I-125 source are completely absorbed by the brass source holder.

9.2. If for any reason the source is dropped when the cap is off, pick up the source by the end opposite the threaded end, being careful not to point the hole from the source window towards you. Pick up the brass source holder cap in your other hand and screw it on the source holder. This will totally shield any radiation coming from the source.

10. DUTIES AND RESPONSIBILITIES

10.1. The authorized users will be responsible for:

10.1.1. Receipt of sources and logging in the source receipt log.

10.1.2. Storage of sources received in the radioactive materials storage area.

10.1.3. Source replacement in the OsteoAnalyzer.

10.1.4. Packaging of sources for shipping and delivering to a carrier for shipment to the manufacturer.

10.1.5. Leak testing of sources in use over six months.

10.2. The Radiation Safety Officer will be responsible for the following:

10.2.1. Assuring that byproduct materials possessed under the license conform to the materials listed on the license.

10.2.2. Assuring that use of the device is only by individuals authorized by the license.

10.2.3. Assuring that all users wear personnel monitoring equipment when required.

10.2.4. Assuring that the sources are properly secured against unauthorized removal at all times when not in use.

10.2.5. Serving as a point of contact to give assistance in case of an emergency, and assuring that proper authorities are notified in case of an emergency.

10.2.6. Assuring that the terms and conditions of the license are met and that required records are periodically reviewed for compliance with NRC regulations and license conditions.

IN-HOUSE TRAINING PROGRAM FOR USERS OF OsteoAnalyzer

1. PERSONNEL PROVIDING TRAINING

1.1. Personnel providing training for users of the Osteon Model SPSHAL10 bone mineral analyzer (OsteoAnalyzer) will be either certified by the American Board of Health Physics or will be licensed by the NRC or agreement state for medical use of the OsteoAnalyzer.

2. OUTLINE OF FORMAL TRAINING

2.1. The formal training program will consist of eight hours of classroom presentation on radiation safety aspects of the OsteoAnalyzer, followed by four hours hands-on training on the OsteoAnalyzer.

2.2. The classroom presentation will cover the basic concepts of radiation protection and control, and applicable regulations, according to the following outline:

2.2.1. Basic Radiation Physics and Instrumentation (3 hours)

- Atomic structure

- Decay process and types of emissions, with emphasis on I-125

- Definitions and units of radioactivity

- Interactions of radiation with matter

- Half-life, inverse square law, and half-value layers

- Decay constant formula and use of decay tables

- Inverse square law formula and examples

- Calculation of radiation dose in air, tissue, and bone

- Radiation dose - dose rate, time and average dose

- Characteristics of sealed sources

2.2.2. Radiation Biology (3 hours)

- Acute and chronic exposure

- Somatic and genetic effects

- Basis of maximum permissible dose

- Typical somatic effects at various dose levels

- Genetic effects and genetically significant dose

- Factors affecting biological damage (dose, dose rate, type of radiation, type of tissue, amount of tissue, biological variation and chemical modifiers)

2.2.3. Radiation Protection

Principles of radiation safety and ALARA management program
The regulations in 10 CFR 19 and 10 CFR 20
License Conditions for radiation safety program
Radioactive shipment receiving, opening, handling, storage, and security procedures
Radiation labels and required posting and documents
Routine proper use, inventory and accountability procedures for sealed sources
Leak test of sealed sources and contamination control
Shipment returns, DOT regulations and supplier instructions and forms
Radiation detection instrumentation
NRC Draft Regulatory Guide "Instructions Concerning Radiation Exposure" and NRC Regulatory Guide 8.13
10 CFR 35 and NRC Regulatory Guide 10.8
Radiation safety references, NCRP and ICRP publications
Sealed source "device specific" manufacturer literature and instructions

2.3. Trainees will be required to pass a written examination with a score of at least 70% before being allowed to proceed to the hands-on portion of the training program.

3. OUTLINE OF HANDS-ON TRAINING

3.1. Hands-on training will be provided by an instructor qualified per 1.1. above.

3.2. Hands-on training will consist of 4 hours of supervised use of the OsteoAnalyzer. The following specific topics will be covered during the hands-on training:

3.2.1. Source receipt, wipe testing, and logging in inventory record.

3.2.2. Source replacement in OsteoAnalyzer.

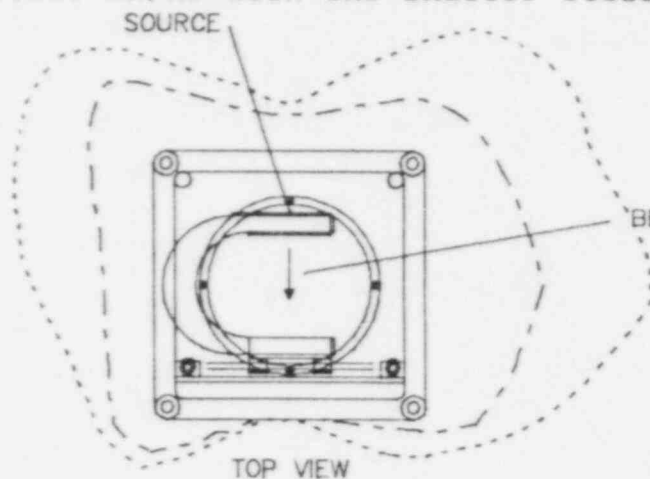
3.2.3. Source packaging for shipping, and shipping.

3.2.4. Source handling and security procedures.

Isodose lines for Osteon, Inc. Model SPSHAXXX bone mineral Analyzer (OsteoAnalyzer).

Readings shown for shutter open and 800 mCi I-125 source in place. Readings taken with Victoreen 490 survey meter and 489-110 pancake probe. Survey meter calibrated specifically for I-125, using two separate sources and source activity data supplied by AECL. Calibration factor of 0.00009 mR/hr per cpm was used, based on gamma factor of 0.7 R-sq.cm./hr-mCi for I-125.

Readings on all surfaces of the analyzer were less than 0.001 mR/hr with the shutter closed.



Performed by: *Philip Manly*
 Title: Certified Health Physicist

Date: 23 Nov 84

LEGEND	
-----	0.1 mr/hr contour
- - - - -	0.2 mr/hr contour
- - - - -	1.0 mr/hr contour
Data corrected to 800 mCi source	
Scale: 1" = 6"	

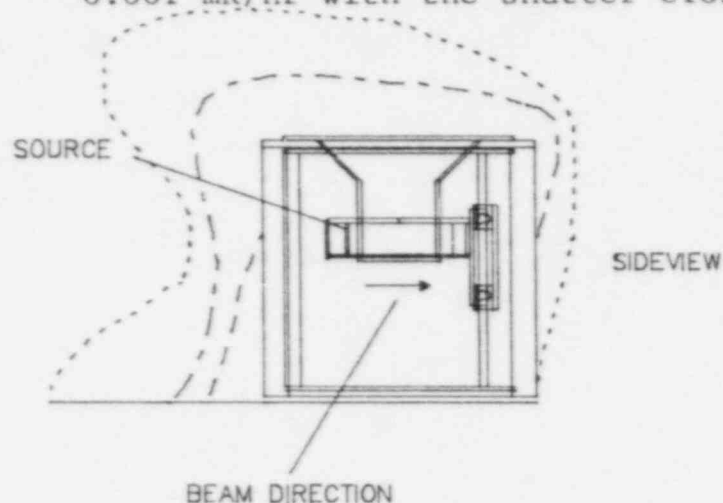
MATERIAL		Osteon, Inc.	
FINISH		TITLE ISODOSE PLOT	
FINISHED TO DIMENSIONS UNLESS SPECIFIED	DRAWN BY		
	CHECKED BY		
	APPROVED BY <i>PM</i>		
NEXT ASSY DRAWING		DRAWING NUMBER	REV
MODEL NUMBER SPSHAXXX			

Figure 1

Isodose lines for Osteon, Inc. Model SPSHAXXX bone mineral Analyzer (OsteoAnalyzer).

Readings shown for shutter open and 800 mCi I-125 source in place. Readings taken with Victoreen 490 survey meterf and 489-110 pancake probe. Survey meterc calibrated specifically for I-125, using two separate sources and source activity data supplied by AECL. Calibration factor of 0.00009 mR/hr per cpm was used, based on gamma factor of 0.7 R-sq.cm./hr-mCi for I-125.

Readings on all surfaces of the analyzer were less than 0.001 mR/hr with the shutter closed.



Performed by: *Philip J Manly*
 Title: Certified Health Physicist
 Date: 23 Nov 84

LEGEND	
-----	0.1 mr/hr contour
- - - - -	0.2 mr/hr contour
- - - - -	1.0 mr/hr contour
Data corrected to 800 mCi source	
Scale: 1" = 6"	

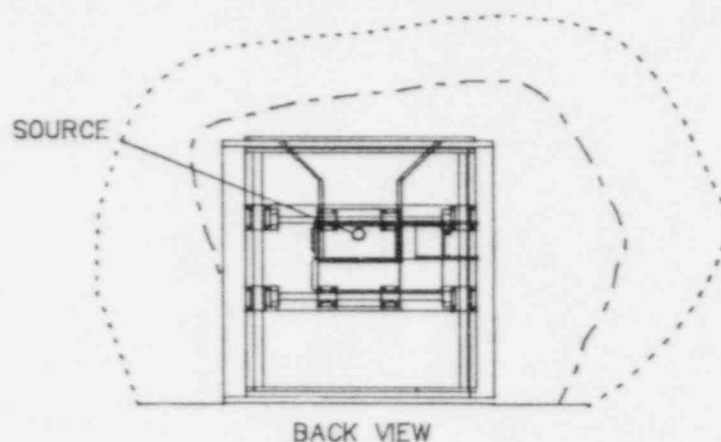
MATERIAL		Osteon, Inc.	
FINISH		TITLE ISODOSE PLOT	
FINISHED TO DIMENSIONS UNLESS SPECIFIED	DRAWN BY		
	CHECKED BY		
	APPROVED BY <i>PJM</i>		
FRACTIONAL DECIMALS 1/100 ANGLES 1/4 DEG		DRAWING NUMBER	
NEXT ASSY DRAWING		REV	
MODEL NUMBER SPSHAXXX			

Figure 2

Isodose lines for Osteon, Inc. Model SPSHAXXX bone mineral Analyzer (OsteoAnalyzer).

Readings shown for shutter open and 800 mCi I-125 source in place. Readings taken with Victoreen 490 survey meterf and 489-110 pancake probe. Survey meterc calibrated specifically for I-125, using two separate sources and source activity data supplied by AECL. Calibration factor of 0.00009 mR/hr per cpm was used, based on gamma factor of 0.7 R-sq.cm./hr-mCi for I-125.

Readings on all surfaces of the analyzer were less than 0.001 mR/hr with the shutter closed.



Performed by: *Philip J Manly*
 Title: Certified Health Physicist
 Date: 23 Nov 84

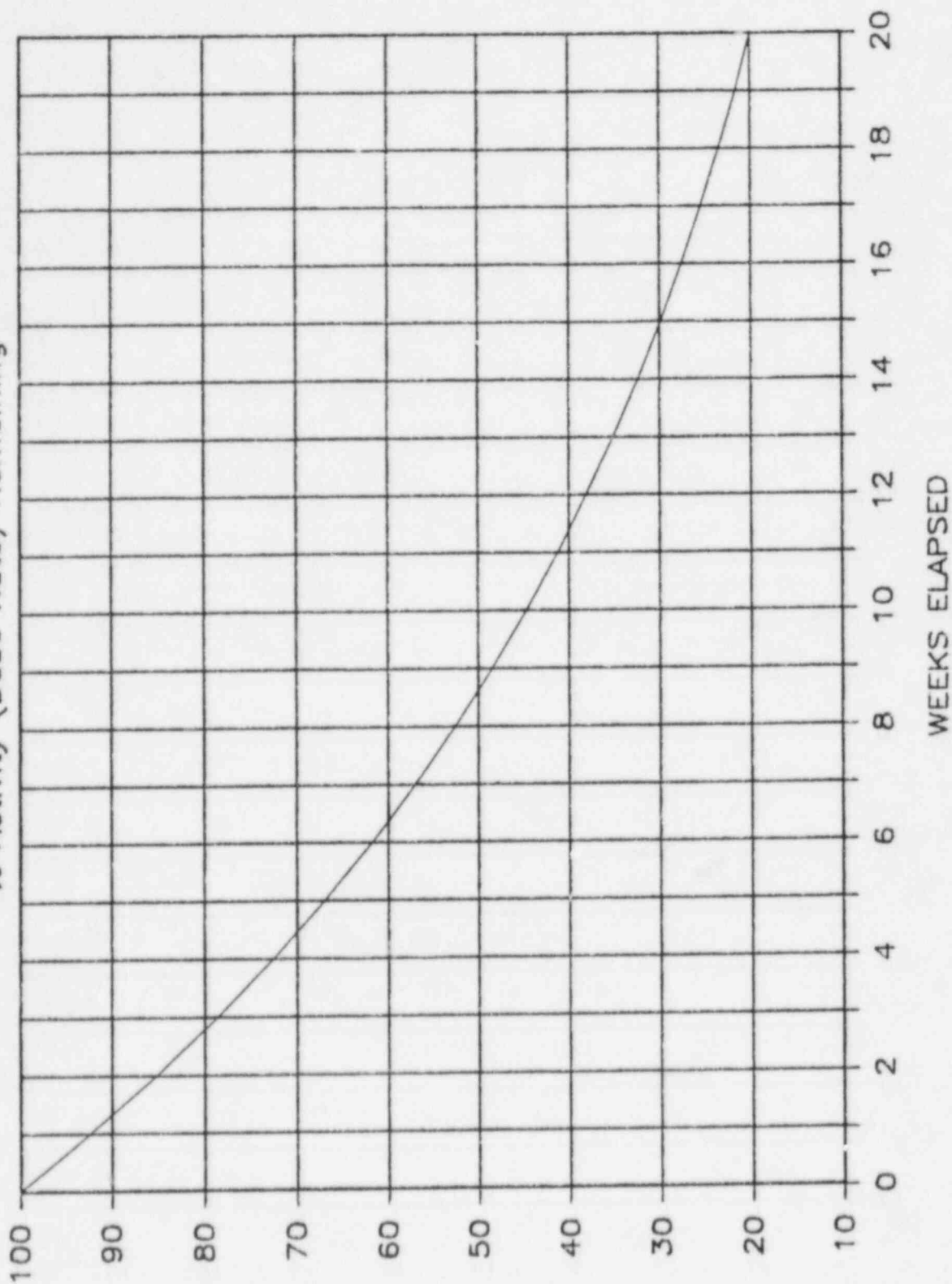
LEGEND	
-----	0.1 mr/hr contour
-----	0.2 mr/hr contour
-----	1.0 mr/hr contour
Data corrected to 800 mCi source	
Scale: 1" = 6"	

MATERIAL		Osteon, Inc.	
FINISH		TITLE	
FINISHED TO DIMENSIONS UNLESS SPECIFIED FRACTIONAL ± 1/64 DECIMAL ± .005 ANGLES ± 1/4 DEG	DRAWN BY	ISODOSE PLOT	
	CHECKED BY		
	APPROVED BY <i>PM</i>		
NEXT ASSEMBLY DRAWING		DRAWING NUMBER	REV
MODEL NUMBER SPSHAXXX			

Figure 3

I-125 Decay Curve

% Activity (Dose Rate) Remaining



% REMAINING

Figure 4

LICENSED MATERIAL

Item 5 - Radioactive Material

Element and mass number: I-125

Chemical and/or physical form: sealed source (AECL C-235 source in AECL C-236 source holder)

Maximum amount which will be possessed: 5 sources at 800 mCi per source

Item 6 - Purposes For Which Licensed Material Will Be Used

Use in Model SPSHAXXX bone mineral analyzer for performance testing and development, training, and demonstration. The Model SPSHAXXX bone mineral analyzer has received custom device approval from the NRC.

RADIATION SAFETY PROGRAM

Item 10 - Radiation Safety Program

1. SURVEY PROGRAM

1.1. The use of the sealed source in the bone mineral analyzer consists of placing the source in a fixed geometry position in the analyzer. Once it is in place, the shielding and beam direction cannot change unless the analyzer suffers some damage.

1.2. A detailed radiation survey has been performed with the source in an OsteoAnalyzer. The results of the survey are shown in Figure 1 to 3, normalized to a full strength 800 mCi source. A decay curve is also provided in Figure 4 so that the radiation levels for any source strength can be estimated from Figures 1 to 3.

2. RECORDS MANAGEMENT PROGRAM

2.1. Records of source receipt and transfer shall be kept for at least 5 years.

2.3. Records of leak tests of sealed sources shall be kept for at least 5 years.

2.4. Personnel exposure records shall be kept indefinitely.

2.5. Records of source disposals shall be kept indefinitely.

2.6. Records shall be reviewed for completeness and accuracy on a semi-annual basis by the Radiation Safety Officer or his designate.

3. LEAK TEST PROCEDURES

3.1. Leak tests shall be performed on sources in use every six months. The leak tests shall be able to detect 0.005 uCi of activity. Results of the leak tests shall be documented. Leak tests shall be performed according to the following procedures:

3.1.1. Take a canvas wipe and wipe it around the joint between the source holder and source cap. Place the wipe in the folded paper envelope used to hold it.

3.1.2. Calibrate the laboratory counter with a mock iodine source. Count the mock iodine source for one minute.

3.1.3. Count background for one minute. Calculate the conversion factor for the detector as follows:

$$K = uCi / (C_s - C_b)$$

uCi = source activity

C_s = source cnts per min

C_b^s = bkgd cnts per min

3.1.4. Remove the source and take a one minute background count. Calculate the minimum detectable activity (MDA) and minimum detectable count rate (MDCR) according to the following formulas:

$$MDCR = 1.64 \times \sqrt{2 \times C_b}$$

$$MDA = K \times 1.64 \times \sqrt{2 \times C_b}$$

3.1.5. Count the wipe for 1 minute. If the measured count rate is less than MDCR, record the activity as <MDA. If the measured count rate is greater than MDCR, calculate and record the actual activity.

3.1.6. With typical counting equipment, this counting procedure will result in a MDA of less than 0.0005 uCi.

4. INSTRUCTION TO PERSONNEL

4.1. Personnel who use the I-125 sealed sources in the OsteoAnalyzer will either be specifically authorized by the license, or will have completed the in-house training program for users of the OsteoAnalyzer.

5. PACKAGE RECEIVING AND OPENING PROCEDURES

5.1. The I-125 sources are also less than Type A quantities of radioactive material. Consequently, no radiation surveys are required on receipt of the package. When shipped from the manufacturer, the packages carry a WHITE-I radioactive label, indicating that radiation levels on the surface are less than 0.5 mR/hr.

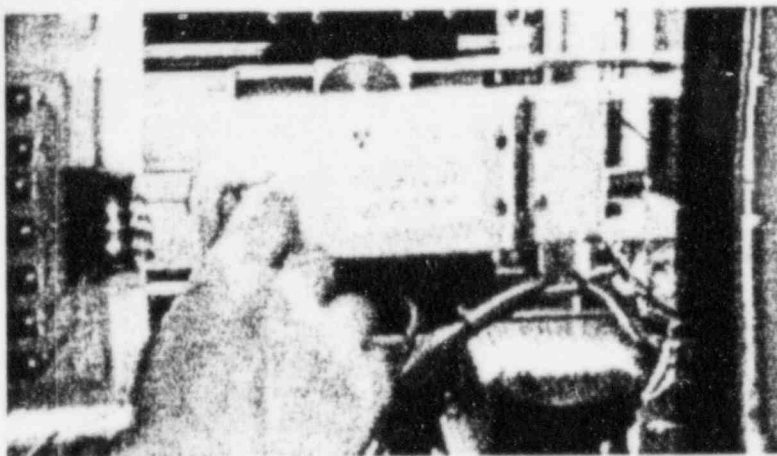
5.2. Open the outer shipping container. Open the inner shipping container with the brass source capsule. Take a canvas wipe and wipe the brass source capsule. Analyze the wipe to verify² there is no removable contamination greater than 200 dpm/100 cm².

5.3. Verify the serial number on the source against the serial number on the shipping documents. Log the receipt of the source into the source receipt log.

5.4. Leave the source in the original shipping container until it is actually installed in the analyzer.

6. SOURCE REPLACEMENT PROCEDURES

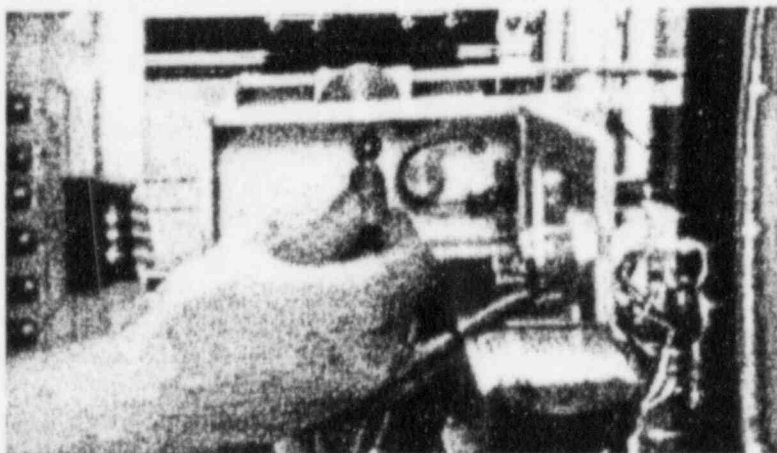
6.1. Remove the outer cover of the scanner unit. Using the key for the source compartment, unlock and remove the cover from the source compartment.



6.2. Unscrew the source from the receptacle in the source compartment. Immediately screw on the brass cap on the source. Make sure the end of the source capsule with the threads is always pointed away from you when the cap is not on.

6.3. Place the source in the shipping container to be returned to the manufacturer.

6.4. Remove the new brass source capsule with the brass cap attached from the shipping container. Unscrew the cap from the source and screw the source into the receptacle in the source compartment. Make sure the end of the source capsule with the threads is always pointed away from you when the cap is not on.



6.5. Using the key, lock the source compartment cover in place. Remove the key and store it in a secure location.

6.6. Replace the cover on the scanner unit.

7. SOURCE PACKAGING AND SHIPPING PROCEDURES

7.1. Place the source with the cap tightly screwed on in the foam insert from the original shipping container.

7.2. Place the foam insert in the original inner container (metal can) and tape the lid on the can with fabric-backed tape.

7.3. Place the metal can in the original outer shipping box and tape the box closed with security tape.

7.4. Remove old shipping labels, packing slips, and other old labels from the box. Make sure the words "RADIOACTIVE MATERIAL", "TYPE 'A' PACKAGE", "I.A.E.A. C.T.C-12B25", and the manufacturer's name and address are still clearly legible on the box.

7.5. Place two new RADIOACTIVE WHITE-I labels over the old ones on the box. Enter I-125 as the contents. Calculate and enter the activity of the source.

7.6. Place a shipping label on the box with the name and address of the facility shipped from and shipped to.

7.7. Write or stamp the words "RADIOACTIVE MATERIAL, N.O.S." and "UN2982" on the box in letters at least 1/2" high.

7.8. Fill out the shipping papers for the shipment. The proper shipping name for the source is "Radioactive Material, N.O.S. (Iodine-125)" and the proper classification is "UN2982".

8. INVENTORY REQUIREMENTS

8.1. An inventory of all sources in use and in storage shall be made every six months. Records of the semi-annual inventories shall be kept.

9. EMERGENCY PROCEDURES

9.1. The low energy gamma and x-rays emitted from the I-125 source are completely absorbed by the brass source holder.

9.2. If for any reason the source is dropped when the cap is off, pick up the source by the end opposite the threaded end, being careful not to point the hole from the source window towards you. Pick up the brass source holder cap in your other hand and screw it on the source holder. This will totally shield any radiation coming from the source.

10. DUTIES AND RESPONSIBILITIES

10.1. The authorized users will be responsible for:

10.1.1. Receipt of sources and logging in the source receipt log.

10.1.2. Storage of sources received in the radioactive materials storage area.

10.1.3. Source replacement in the OsteoAnalyzer.

10.1.4. Packaging of sources for shipping and delivering to a carrier for shipment to the manufacturer.

10.1.5. Leak testing of sources in use over six months.

10.2. The Radiation Safety Officer will be responsible for the following:

10.2.1. Assuring that byproduct materials possessed under the license conform to the materials listed on the license.

10.2.2. Assuring that use of the device is only by individuals authorized by the license.

10.2.3. Assuring that all users wear personnel monitoring equipment when required.

10.2.4. Assuring that the sources are properly secured against unauthorized removal at all times when not in use.

10.2.5. Serving as a point of contact to give assistance in case of an emergency, and assuring that proper authorities are notified in case of an emergency.

10.2.6. Assuring that the terms and conditions of the license are met and that required records are periodically reviewed for compliance with NRC regulations and license conditions.

IN-HOUSE TRAINING PROGRAM FOR USERS OF OsteoAnalyzer

1. PERSONNEL PROVIDING TRAINING

1.1. Personnel providing training for users of the Osteon Model SPSHAL10 bone mineral analyzer (OsteoAnalyzer) will be either certified by the American Board of Health Physics or will be licensed by the NRC or agreement state for medical use of the OsteoAnalyzer.

2. OUTLINE OF FORMAL TRAINING

2.1. The formal training program will consist of eight hours of classroom presentation on radiation safety aspects of the OsteoAnalyzer, followed by four hours hands-on training on the OsteoAnalyzer.

2.2. The classroom presentation will cover the basic concepts of radiation protection and control, and applicable regulations, according to the following outline:

2.2.1. Basic Radiation Physics and Instrumentation (3 hours)

- Atomic structure
- Decay process and types of emissions, with emphasis on I-125
- Definitions and units of radioactivity
- Interactions of radiation with matter
- Half-life, inverse square law, and half-value layers
- Decay constant formula and use of decay tables
- Inverse square law formula and examples
- Calculation of radiation dose in air, tissue, and bone
- Radiation dose - dose rate, time and average dose
- Characteristics of sealed sources

2.2.2. Radiation Biology (3 hours)

- Acute and chronic exposure
- Somatic and genetic effects
- Basis of maximum permissible dose
- Typical somatic effects at various dose levels
- Genetic effects and genetically significant dose
- Factors affecting biological damage (dose, dose rate, type of radiation, type of tissue, amount of tissue, biological variation and chemical modifiers)

2.2.3. Radiation Protection

Principles of radiation safety and ALARA management program
The regulations in 10 CFR 19 and 10 CFR 20
License Conditions for radiation safety program
Radioactive shipment receiving, opening, handling, storage,
and security procedures
Radiation labels and required posting and documents
Routine proper use, inventory and accountability procedures
for sealed sources
Leak test of sealed sources and contamination control
Shipment returns, DOT regulations and supplier instructions
and forms
Radiation detection instrumentation
NRC Draft Regulatory Guide "Instructions Concerning
Radiation Exposure" and NRC Regulatory Guide 8.13
10 CFR 35 and NRC Regulatory Guide 10.8
Radiation safety references, NCRP and ICRP publications
Sealed source "device specific" manufacturer literature and
instructions

2.3. Trainees will be required to pass a written examination with a score of at least 70% before being allowed to proceed to the hands-on portion of the training program.

3. OUTLINE OF HANDS-ON TRAINING

3.1. Hands-on training will be provided by an instructor qualified per 1.1. above.

3.2. Hands-on training will consist of 4 hours of supervised use of the OsteoAnalyzer. The following specific topics will be covered during the hands-on training:

3.2.1. Source receipt, wipe testing, and logging in inventory record.

3.2.2. Source replacement in OsteoAnalyzer.

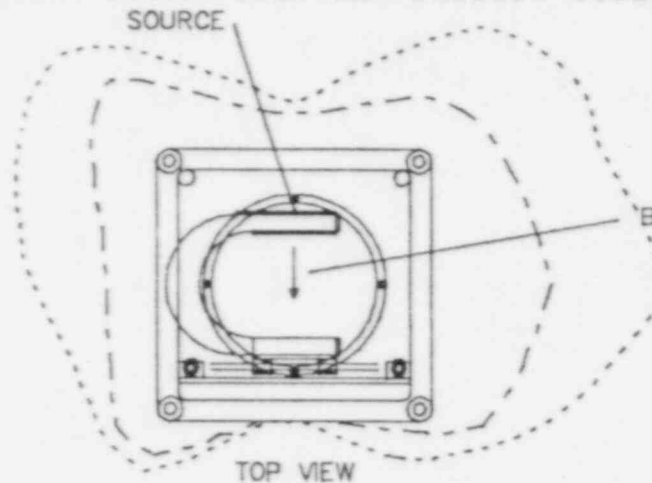
3.2.3. Source packaging for shipping, and shipping.

3.2.4. Source handling and security procedures.

Isodose lines for Osteon, Inc. Model SPSHAXXX bone mineral Analyzer (OsteoAnalyzer).

Readings shown for shutter open and 800 mCi I-125 source in place. Readings taken with Victoreen 490 survey meterf and 489-110 pancake probe. Survey meterc calibrated specifically for I-125, using two separate sources and source activity data supplied by AECL. Calibration factor of 0.00009 mR/hr per cpm was used, based on gamma factor of 0.7 R-sq.cm./hr-mCi for I-125.

Readings on all surfaces of the analyzer were less than 0.001 mR/hr with the shutter closed.



Performed by: *Philip Manly*
 Title: Certified Health Physicist

Date: 23 Nov 84

LEGEND

..... 0.1 mr/hr contour
 - - - - - 0.2 mr/hr contour
 - - - - - 1.0 mr/hr contour
 Data corrected to 800 mCi source

Scale: 1" = 6"

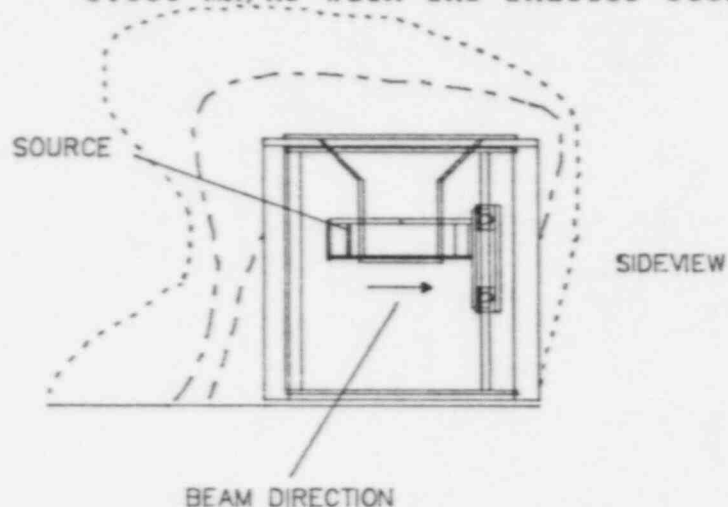
MATERIAL		Osteon, Inc.		
FINISH		TITLE		
CHECKED UNLESS SPECIFIED DATE 1-1/84 BY 1-1/84		DRAWN BY CHECKED BY APPROVED BY <i>PM</i>	ISODOSE PLOT	
NEXT ASSY DRAWING		DRAWING NUMBER		REV
MODEL NUMBER SPSHAXXX				

Figure 1

Isodose lines for Osteon, Inc. Model SPSHAXXX bone mineral Analyzer (OsteoAnalyzer).

Readings shown for shutter open and 800 mCi I-125 source in place. Readings taken with Victoreen 490 survey meterf and 489-110 pancake probe. Survey meterc calibrated specifically for I-125, using two separate sources and source activity data supplied by AECL. Calibration factor of 0.00009 mR/hr per cpm was used, based on gamma factor of 0.7 R-sq.cm./hr-mCi for I-125.

Readings on all surfaces of the alyzer were less than 0.001 mR/hr with the shutter closed.



Performed by: *Philip J Mauly*
 Title: Certified Health Physicist
 Date: 23 Nov 84

LEGEND

----- 0.1 mr/hr contour
 - - - - - 0.2 mr/hr contour
 - - - - - 1.0 mr/hr contour
 Data corrected to 800 mCi source

Scale: 1" = 6"

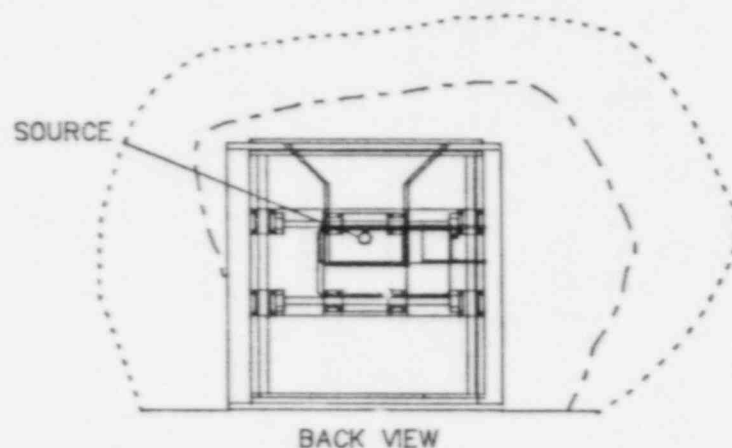
MATERIAL		Osteon, Inc.	
FINISH		TITLE	
DESIGNED BY CHECKED BY UNLESS SPECIFIED FRACTIONAL 1/16 DECIMAL 0.001 ANGLES 1/4 DEG		ISODOSE PLOT	
DRAWN BY		DRAWING NUMBER	
CHECKED BY		REV	
APPROVED BY <i>PM</i>			
NEXT ASSTY DRAWING			
MODEL NUMBER SPSHAXXX			

Figure 2

Isodose lines for Osteon, Inc. Model SPSHAXXX bone mineral Analyzer (OsteoAnalyzer).

Readings shown for shutter open and 800 mCi I-125 source in place. Readings taken with Victoreen 490 survey meterf and 489-110 pancake probe. Survey meterc calibrated specifically for I-125, using two separate sources and source activity data supplied by AECL. Calibration factor of 0.00009 mR/hr per cpm was used, based on gamma factor of 0.7 R-sq.cm./hr-mCi for I-125.

Readings on all surfaces of the analyzer were less than 0.001 mR/hr with the shutter closed.



Performed by: *Philip J. Manly*
 Title: Certified Health Physicist
 Date: 23 Nov 84

LEGEND	
.....	0.1 mr/hr contour
-----	0.2 mr/hr contour
-----	1.0 mr/hr contour
Data corrected to 800 mCi source	
Scale: 1" = 6"	

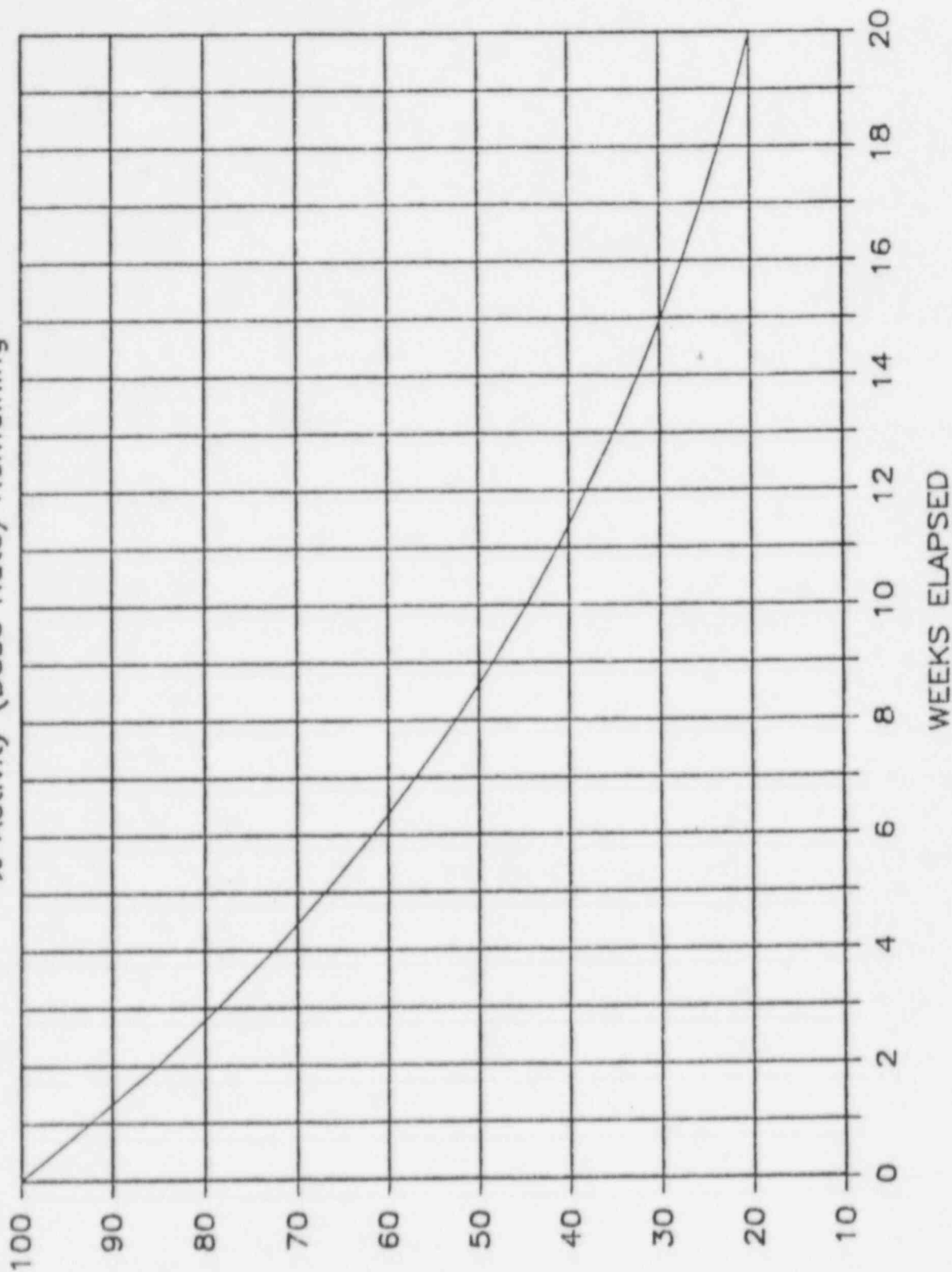
MATERIAL		Osteon, Inc.	
FINISH			
FINISHED TO SPECIFICATION UNLESS SPECIFIED	DRAWN BY	TITLE ISODOSE PLOT	
	CHECKED BY		
	APPROVED BY <i>PTM</i>		
FRACTIONAL 1-1/84 DATE 1-1/84 DEC			
NEXT ASSY DRAWING		DRAWING NUMBER	
MODEL NUMBER SPSHAXXX		REV	

Figure 3

70246

I-125 Decay Curve

% Activity (Dose Rate) Remaining



% REMAINING

Figure 4

70246